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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
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ART UNIT	PAPER NUMBER
1648	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/737,288	WEINBERG, AARON	
	Examiner	Art Unit	
	Louise Humphrey, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-39* is/are pending in the application.

4a) Of the above claim(s) *8-12 and 20-39* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7 and 13-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 December 2003* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10/12/04, 02/03/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The Office acknowledges the receipt of Applicant's election filed on 03 February 2006.

Election/Restrictions

Applicant elects Group I, claims 1-19, with traverse.

The traversal is on the grounds that: (1) claims 1 and 2 have been classified into both Groups I and II; (2) Groups I and II have been misclassified; and (3) the sequences are not structurally different from each other. Applicant's traversal is unpersuasive for the following reasons:

Claims 1 and 2 are linking claims that contain two inventions. See M.P.E.P. §809 [R-3]. Therefore, it is appropriate to restrict within the claims.

Applicant's traversal is based upon the classification number assigned to each Group. It is unclear where Applicant obtained the definition for class 424, subclass 9.2. However, Applicant's allegation of Examiner's misclassification of the claims does not address or support Applicant's traversal of the restriction requirement. The PTO classification is merely an administrative convenience and is not dispositive of the relatedness of applications. Even if the Groups were placed in the same class and subclass, the searches are not co-extensive and thus would be an undue burden on Office resources.

Applicants' contention of the common structure and utility to the sequences claimed in the application is improper because each nucleotide sequence is not considered to be a proper member of a Markush group. See M.P.E.P. § 803.02. *In re*

Harnish, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility.

As indicated in the prior Office Action, the instant claims are drawn to multiple oligonucleotides, which are considered to be unrelated, since each sequence claimed is structurally and functionally independent and distinct due to their unique nucleotide sequence. As such, the sequences in the instant claims are not considered to constitute a proper Markush group/genus, and are therefore subject to restriction. Furthermore, a search of more than one of the sequences present in these claims presents an undue burden on the Patent and Trademark Office due to the complex nature of the search in terms of computer time needed to perform the search and the subsequent analysis of the search results by the examiner. In view of the foregoing, one sequence is considered to be a reasonable number of sequences for examination.

The instant amino acid sequences vary in length from 41 to 121 residues. The vast size difference in the primary structure contributes to differences in the secondary structures, i.e. alpha helices and beta sheets, the tertiary structure, and the quaternary structure of the protein folding. In other words, as already indicated in the prior Office Action, each SEQ ID NO represents a structurally different polypeptide encoded by a different polynucleotide, even though they all belong to the same protein family possessing the same general function. The length and the overall three-dimensional structure of the polypeptide determine the binding specificity and immunogenicity of

each polypeptide. Therefore, each SEQ ID NO is a separate invention. Accordingly, applicants are required to elect one sequence.

The restriction among the different claimed methods is maintained.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-39 are pending. Claims 8-12 and 20-39 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention and species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 03 February 2006.

Claims 1-7 and 13-19 are examined in the instant application and will be read to the extent of the elected sequences, SEQ ID NO:1 and SEQ ID NO:7.

Information Disclosure Statement

Two initialed and dated copies of Applicant's IDS form 1449, filed on 12 October 2004 and 3 February 2006, are attached to the instant Office action.

Drawings

The drawings are objected to because in Figure 1 the word "defensins" is missing an "e" and the phrase "Buffer used to incubated HIV + hBD" is grammatically incorrect. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an

amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

The abstract of the disclosure is objected to because it is merely restating the title and does not disclose the invention. Correction is required. See MPEP §608.01(b).

Double patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422

F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-7 and 13-19 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7 and 14-20 of copending Application No. 10/891,825. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims recite exactly the same limitations of method steps, comprising administering to a subject an effective amount of agent or contacting a cell with an effective amount of an agent, of the agent, human Beta Defensin (HBD), of the route of administration, of the site of administration, and of the formulation of the agent. The only difference between the instant claims and the copending claims is the wording of the preamble of two claims: the instant claim 1 recites a method for inhibiting HIV infection in a subject, whereas the copending claim 1 recites a method for treating an HIV infection in a subject; the instant claim 2 recites a method for inhibiting the contraction of an HIV infection in a subject, whereas the copending claim 2 recites a method for decreasing the likelihood that a subject will contact an HIV infection. The actual method steps are the same. Therefore, copending claims 1-7 and 14-20 fall entirely within the scope of the instant claims 1-7 and 13-19 or, in other words, claims 1-7 and 13-19 are anticipated by claims 1-7 and 14-20 of the application serial No. 10/891,825.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. §112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 13 is rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 13 recites "a 50% effectives at a concentration of about 10 micromolar or less" but does not recite the system where the IC_{50} is measured.

Clarification and/or correction are required.

Claim Rejections - 35 USC § 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. §112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5 and 14-19 are rejected under 35 U.S.C. §112, first paragraph, because the specification, while being enabling for *in vitro* inhibition of HIV entry into a cell culture, does not reasonably provide enablement for the *in vivo* inhibition of HIV infection, HIV contraction, and HIV entry into a cell inside a subject, especially if the subject is a human. The specification does not enable any person skilled in the art to

which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

"[T]o be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation.'" *Genentech Inc. v. Novo Nordisk* 108 F.3d 1361, 1365, 42 USPQ2d 1001, 1004 (Fed. Cir. 1997); *In re Wright* 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993); See also *Amgen Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1212, 18 USPQ2d 1016, 1026 (Fed. Cir. 1991); *In re Fisher* 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). Further, in *In re Wands* 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) the court stated:

> Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in *Ex parte Forman* [230 USPQ 546, 547 (BdPatAppInt 1986)]. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. *In re Wright*, 999 F.2d 1557,1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993).

The nature of the instant invention is a method for inhibiting HIV infection and the contraction of HIV infection in a subject, and HIV entry into a cell. The breadth of the

instant claims is so broad that it encompasses both HIV treatments and prophylactics for all living subjects including mammals and even humans.

The guidance presented in the specification is limited to *in vitro* cell-free assays and cell culture assays, which all have the art-recognized limitation of high levels of assay variability between virus cultures. All *in vitro* tests are unreliable in detecting the drug susceptibility of minority HIV-1 variants in the virus population. Resistant mutants may not persist at detectable levels in the absence of drug selection pressure (Martinez-Picado, 1998, pages 84, 85, and 87), which increases the complexity in extrapolating from *in vitro* to *in vivo* test results.

The clinical relevance of an *in vitro* result of cell viability with less HIV viral population is unpredictable because an *in vitro* system is over-simplified compared to the body of an HIV-infected subject. An *in vitro* assay does not correlate with the complex interactions of natural HIV infections in subjects such as humans and thus, does not relate to protection against any strain and/or clade of HIV-1, especially in humans. Due to the highly unpredictable nature of HIV-infection, extrapolating from *in vitro* cells to whole organisms without *in vivo* validation is hazardous and unpredictable.

The state of the art of development of HIV inhibitor/vaccine is highly unpredictable, since HIV replicates rapidly with a high mutational frequency and creates diverse 'quasi-species', which are favored by the Darwinian selective pressures. Therefore, efforts to develop effective treatments and vaccines must overcome the complex evolutionary dynamics in HIV-infected individuals and within affected populations.

Furthermore, the problem to selectively target cells *in vivo* is still one of the most difficult obstacles to overcome. For example, upon systemic administration, the viral particles may bind to many cells they encounter *in vivo*; and consequently, would be diluted out before reaching their targets.

Considering the lack of data or working examples in the specification, the broad scope of the claims, the complex state and nature of the art, and the teachings regarding unpredictability in this art, one skilled in the art would have to engage in an undue amount of experimentation to practice the claimed method *in vivo* without undue experimentation. "Experimentation must not require ingenuity beyond that to be expected of one of ordinary skill in the art." See *Fields v. Conover*, 443 F.2d 1386, 170 USPQ 276 (CCPA 1970). In the instant case, a pharmaceutical HIV-vaccine comprising recombinant adenovirus particles is not considered routine in the art and, without sufficient guidance to elicit therapeutic effects, the experimentation left to those skilled in the art is undue or unreasonable under the circumstances. It is noted that the unpredictability of a particular area may alone provide reasonable doubt as to the accuracy of the broad statement made in support of enablement of claims. See *Ex parte Singh*, 17 USPQZd 1714 (BPAI 1991).

Given the divergence of *in vitro* and *in vivo* HIV-specific immune responses, the clinical relevance of the disclosed measurements in the instant application is uncertain. One skilled in the art would be burdened with an undue quantity of *in vivo* experiments in order to make and use the current invention since the applicants have not provided any clear-cut evidence to demonstrate that the claimed hBD can prevent or treat HIV

infection in any subjects. Absent working examples and specific teachings of the clinical efficacy, therapeutic index, and pharmacokinetic properties of the hBDs, those in the art would not be able to use the claimed method. The instant invention, based on the evidence as a whole, in light of the factors articulated by the court in *In re Wands*, lacks an enabling disclosure.

Claims 6 and 7 are rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

The claims are directed to a method for inhibiting HIV infection and the contraction of HIV infection in a subject, and HIV entry into a cell, wherein said HBD-2 agent is a polypeptide comprising an amino acid sequence at least 90% identical to an amino acid sequence selected from the group consisting of: SEQ ID NO:1 and SEQ ID NO:2, and wherein further said HBD-2 agent is a polypeptide encoded by a nucleic acid that is at least 90% identical to a nucleic acid selected from the group consisting of: SEQ ID NOs:4-7.

To provide adequate written description and evidence of possession, the specification must provide sufficient distinguishing identifying characteristics. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation,

methods of making the claimed product, or any combination thereof. In this case, the only factor present is a single amino acid sequence of an isolated protein. Specifically, the claims contain the phrases "at least 90% identical to," which is not described in the specification in any manner. The specification only provides description for a method of inhibiting HIV entry into a cell comprising contacting the cell with a full-length hBD's (pages 46-49).

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* on page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure and function of the encompassed genus of undefined nucleotide and peptide fragments. Therefore, conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation or synthesis. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016. Therefore, only the nucleotide encoding the full-length hBD-2 has been described.

The patent law requires that a patent contain a written description of a claimed invention independent of the requirements to enable one skilled in the art to make and use the invention. See e.g., *Invitrogen Corp. v. Clontech Labs, Inc.*, 429 F.3d 1052, 1071 n.17 (Fed. Cir. 2005) ("written description is distinct from the enablement requirement"); *Capon v. Eshhar*, 418 F.3d 1349, 1360 (Fed. Cir. 2005) ("although the legal criteria of enablement and written description are related and are often met by the same disclosure, they serve discrete legal requirements").

Therefore, claims 6 and 7 do not meet the written description provision of 35 U.S.C. §112, first paragraph.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. §102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. §102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. §102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. §102(e)).

Claims 1-7 and 13-15 are rejected under 35 U.S.C. §102(b) as being anticipated by Olsen *et al.* (WO 98/51794 A1).

The instant claims read on a method for inhibiting HIV infection, HIV contraction, and HIV entry into a cell in the culture, comprising administering to or contacting the cell with an effective amount of a human Beta defensin-2 (hBD-2) agent.

Olsen *et al.* teach the claimed hBD2 with the same amino acid sequences as the claimed SEQ ID NO: 1 (the mature protein) and SEQ ID NO:2 (full length protein before maturation), and the same nucleic acid sequence as SEQ ID NO: 7. See page 13, lines 3-6, and page 24, lines 10-15. Olsen *et al.* emphasizes the antimicrobial properties of the peptides and its use for diagnosis or treatment of various immune system-related disorders, which reads on the claimed anti-HIV method. See, for example, page 29, lines 18-21. Since the Olsen peptide has exactly the same sequence identity as the claimed peptide, the 50% effective concentration is the same as claimed. Olsen *et al.* further teach homologous peptides and nucleotides with at least 90% identity. See pages 14-15. Olsen *et al.* also teach the modes of administration. See page 32, lines 1-16. Thus, the instant invention is anticipated by Olsen *et al.*

Claims 1-4 and 14-19 are rejected under 35 U.S.C. §102(e) as being anticipated by Wilson *et al.* (US 6,399,370).

The instant claims read on a method for inhibiting HIV infection, HIV contraction, and HIV entry into a cell in the culture, comprising administering to or contacting the cell with an effective amount of a Beta Defensin (BD) agent.

Wilson *et al.* teach the human beta defensin 1 (hBD-1) and suggest using hBD-1 in the treatment of HIV. See column 15, lines 6-19. Wilson *et al.* specifically teach the route of administration and formulations of the hBD-1. See column 15, lines 31-47. Thus, the instant invention is anticipated by Wilson *et al.*

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. §103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 3-5 are rejected under 35 U.S.C. §103(a) as being unpatentable over Wilson *et al.* (US 6,399,370).

Claim 5 further limits the instant method invention to administering an hBD-2.

Wilson *et al.* do not specifically teach administering an hBD-2 but teach other defensin molecules encoded by other defensin genes which may be isolated by the skilled artisan. See column 8, lines 38-60, and column 10, lines 44-54.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to isolate hBD-2 using the methods suggested by Wilson *et al.* One of ordinary skill in the art would have been motivated to make that combination because a gene encoding a defensin obtained from other cells or tissue may have a higher level of antimicrobial activity, and reasonably would have a reasonable expectation of success because Wilson *et al.* teach how to identify other defensin and

determine its activity and even provide the DNA probes for screening the genomic libraries obtained from other human cells and tissues. Thus, claims 1-5 are obvious over Wilson *et al.* (US 6,399,370), absent unexpected results to the contrary.

Remarks

No claim is allowable.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louise Humphrey, Ph.D., whose telephone number is 571-272-5543. The examiner can normally be reached on Mon-Fri, 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902.

Louise Humphrey, Ph.D.
Patent Examiner

JEFFREY STUCKER
PRIMARY EXAMINER

14 February 2006